

K081112

## 5. 510(k) Summary as required by 21 CFR 807.92

### 5.1. Submitter of 510(k)

510(k) owner's name : Isodose Control BV  
 address : Maxwellstraat 16  
 6716 BX Ede  
 The Netherlands  
 phone : +31 318 502950  
 fax : +31 318 502528  
 name of contactperson : Hub van de Bergh  
 e-mail : [hvandebergh@isodosecontrol.com](mailto:hvandebergh@isodosecontrol.com)  
 date the summary was prepared : April 14, 2008

JUL 29 2008

### 5.2. Device: Flexiplan

name of the device / trade or proprietary name: **Flexiplan**  
 common or usual name: Brachytherapy Treatment Planning System  
 classification name: Remote controlled radionuclide applicator system  
 (per 21 CFR section 892.5700 Product code MUJ)

### 5.3. Legally Marketed Device(s)

The Flexitron device can be shown to be substantial equivalent to the legally marketed devices cited in the table below.

Device	Manufacturer	510(k) #
PLATO BPS	Nucletron B.V.	K983343
BrachyVision	Varian Medical Systems Inc	K992762

### 5.4. Description of the Device

#### 5.4.1. Flexiplan

Flexiplan is a software package which runs on a Windows – based PC and is used by medical professionals to create a radiation therapy plan based on the input entered by the operator. The isotopes used in the calculations match those which are normally used in High Dose Rate (HDR) and Pulsed Dose Rate (PDR) Remote Afterloaders. The software offers tools to enhance imported images and offers contouring of the planned target volume and organs at risk. The main use of Flexiplan is to calculate the required dwell times at the pre – determined dwell positions in a uniform way so that the Planning Target Volume (PTV) is treated with the prescribed dose while sparing the Organs At Risk (OAR). Flexiplan can reconstruct one or more applicators. Based on the contoured target volume and the prescription dose, Flexiplan will calculate the optimal dose distribution for the tumor volume. Evaluation tools are available to qualify of the proposed treatment. The therapy planning is then transferred from the Flexiplan to the Afterloader. The Flexiplan software is intended to be used with the Flexitron Brachytherapy Remote Controlled Afterloading Device.

The Flexiplan System comprises subjoined listed subsystems:

- **Personal Computer**  
It executes the Flexiplan software.
- **Monitor**  
To visualise the treatment planning process.
- **Keyboard**  
To enter treatment data.
- **Mouse**  
To select objects on the screen

The PC is used to execute the Flexiplan software and runs under Windows XP Professional / Vista. The hard disk stores patient data and the built in DVD-RW is used for making backup of the Patient Data. The PC can be connected to the hospital network to import Patient Image Data.

#### **5.4.2. Accessory: Film Scanner**

The Film Scanner allows the user to scan in an X-Ray image to present it on the screen to visualise the implant.

#### **5.4.3. Accessory: Printer**

The Printer allows for hard copy of the patients treatment plan and other stored data.

#### **5.4.4. Accessory: Pen Tablet**

The Pen Tablet acts as an alternative replacement for the mouse enabling the user to outline more accurately and faster a contour on the monitor.

#### **5.4.5. Accessory: Touch Panel**

The Touch Panel acts as an alternative replacement for the mouse enabling the user to outline more accurately and faster a contour on the monitor.

### **5.5. Intended use of the Device**

The Flexiplan is used for the creation of treatment plans for High Dose Rate and Pulsed Dose Rate remote afterloader based brachytherapy. Flexiplan will calculate a proposed treatment course based on imported clinical images and other user entered data. Flexiplan also supports the evaluation of clinical images in calculating the local and global doses.

### **5.6. Technological characteristics of device compared to the predicate device**

The Flexiplan Brachytherapy Treatment Planning System has similar technological characteristics compared to the legally marketed predicate devices listed above.

All these devices are based on a computer system, a monitor for data visualisation, keyboard and mouse for data entry.

### **5.7. Substantial Equivalence**

From the discussion in previous paragraphs it can be concluded that the Flexiplan Brachytherapy Treatment Planning System has similar technological characteristics compared to the legally marketed predicate devices listed in paragraph 5.3.

The differences between Flexiplan and predicate devices do not concern the basic principle of operation nor does it adversely affects the safety or effectiveness of the device.

The intended use of Flexiplan and predicate devices are the same.

The conclusion is that Flexiplan is substantial equivalent to the legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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Mr. Hub van de Bergh  
Quality Assurance & Regulatory Affairs Officer  
Isodose Control B.V.  
PO Box 615, 3900 AP Veenendaal  
Landjuweel 11, 3905 PE  
THE NETHERLANDS

**JUL 29 2008**

Re: K081112

Trade/Device Name: Flexiplan  
Regulation Number: 21 CFR 892.5700  
Regulation Name: Remote controlled radio-nuclide applicator system  
Regulatory Class: II  
Product Code: MUJ  
Dated: April 14, 2008  
Received: April 30, 2008

Dear Mr. Hub van de Bergh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

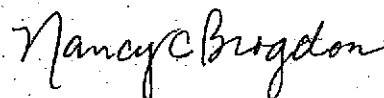
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K081112

Device Name: Flexiplan

Indications for Use:

Flexiplan is a Brachytherapy Treatment Planning System used by medical professionals. Flexiplan is used for the creation of HDR or PDR treatment plans for remote afterloader based brachytherapy. It especially supports the Flexitron Remote Afterloader from Isodose Control. Flexiplan calculates a proposed treatment course based on imported clinical images and other user entered data. Flexiplan supports the evaluation of clinical images in calculating the local and global dose to organs at risk and target volume.

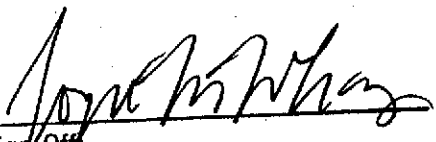
Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K081112